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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,346	01/23/2001	Pamela L. Plouhar	26502-67310	3293

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BARNES & THORNBURG
1313 Merchants Bank Building
11 South Meridian Street
Indianapolis, IN 46204

EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/01/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

NYK

Office Action Summary

Application No.

09/767,346

Applicant(s)

PLOUHAR ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 21, 2003 has been entered.

In the response filed May 21, 2003, Applicants argued that present Figures 4 and 5 disclose a 4-layer construct and that Figures 11 to 13 disclose other multiple layer constructs. Although that Examiner agrees that a 4-layer construct is disclosed, the Examiner does not agree that Figure 11 discloses a 10-layer graft because the lines therein are too unclear. However, Figures 12 and 13 clearly disclose their respective layers of 8 and 6 layers respectively.

Furthermore, although the specification seems to suggest only higher numbers of about 10 or about 50 or more layers, the Examiner decided that Figures 4, 5, 12, and 13 fairly disclose constructs with as few as four layers. For this reason, the claims were determined to have an effective filing date of April 5, 1996.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (US 5,782,915) or Kurland (US 4,585,458) in view of Patel et al (US 5,711,969)

Stone discloses a method of removing the cartilage of a joint down to the bleeding bone bed to create a defect site and then teaches covering the defect site with a tissue as claimed; see column 6, lines 6-15. Likewise, Kurland teaches removing the joint or cartilage tissue to create a defect and then replacing the same with a tissue graft; see Figure 18 and column 7, lines 13-25. However, both Stone and Kurland fail to disclose using a 4 to about 200 layer submucosa tissue graft as claimed. However, Patel teaches that it was known to repair connective tissue with an 8-layer thick submucosa graft; see column 1, lines 16-32 and Example 2. Therefore, it is the Examiner's position that it would have been obvious to use 8-layer submucosa grafts in the Kurland or Stone methods because the 8-layer submucosa grafts have superior strength and ingrowth capabilities as taught by Patel.

With regard to claims 50-52, Stone and Kurland fails to specify the type of joint repaired or the type of cartilage removed as claimed. However, since Stone and Kurland teaches generic removal of cartilage tissue, the removal of specific types would have been considered prima facie obvious absent some showing of criticality or unexpected result.

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (US 5,782,915) in view of Patel et al (US 5,711,969)

Stone discloses a method of removing the cartilage of a joint down to the bleeding bone bed to create a defect site and then teaches covering the defect site with

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a tissue as claimed; see column 6, lines 6-15. However, Stone fails to disclose using a 4 to about 200 layer submucosa tissue graft as claimed. However, Patel teaches that it was known to repair connective tissue with an 8-layer thick submucosa graft; see column 1, lines 16-32 and Example 2. Therefore, it is the Examiner's position that it would have been obvious to use 8 layer submucosa grafts in the Stone method because the 8-layer submucosa has superior strength and ingrowth capabilities as taught by Patel.

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (US 5,782,915) in view of Kurland (US 4,585,458) and Patel et al (US 5,711,969)

Stone discloses a method of removing the cartilage of a joint down to the bleeding bone bed to create a defect site and then teaches covering the defect site with a tissue as claimed; see column 6, lines 6-15. However, Stone fails to disclose using a 4 to about 200 layer submucosa tissue graft and how the fibrin clot is used to hold the graft in place as claimed. However, Kurland teaches that it was known to use a barrier layer between the tissue and defect to aid in the attachment of the laminate to the bone; see column 7, lines 13-25. Furthermore, Patel teaches that it was known to repair connective tissue with an 8-layer thick submucosa graft; see column 1, lines 16-32 and Example 2. Therefore, it is the Examiner's position that it would have been obvious to use 8-layer submucosa grafts in the Stone method because the 8-layer submucosa grafts have superior strength and ingrowth capabilities as taught by Patel. Furthermore, it would have been obvious to put the fibrin clot between the tissue graft and the defect

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for the same reasons that Kurland does the same with his barrier layer and in order to encourage clotting at the bleeding defect site.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
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